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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,821	11/13/2000	Todd M. Kinsella	A-70036/RMS/JJD	9149

959 7590 08/26/2003

LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER

PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 08/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
**09/712,821**

Applicant(s)  
**Kinsella**

Examiner  
**Padmashri Ponnaluri**

Art Unit  
**1639**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Jun 6, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-37 is/are pending in the application.
- 4a) Of the above, claim(s) 21-24, 28-31, 32-37 (inpart) is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 13-20, 25-27, 32-37 (inpart) are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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1. The reply filed on 2/5/03, paper number 17 and the amendment and response filed on 6/6/03 have been considered and entered into the application. To make the record clear examiner would like to withdraw the previous restriction requirement. Examiner apologizes for the inconvenience caused by the confusion.

*To clear the issues the different communications in this application are reiterated. Inventions of group I, drawn to 'a composition comprising a retro viral vector comprising nucleic acid encoding HBEGF fused to nucleic acid encoding a GFP' was examined on merits and an office action was mailed to applicants 6/4/02.*

*Applicants in response to the office action canceled all the elected claims and added new claims which are drawn to several different and distinct vectors, which are in a way broader than the initial composition comprising retro viral vectors comprising HBEGF and GFP.*

*Examiner has restricted the different vectors (mailed on 11/26/02), applicants have elected group II, claims 21-24, 32-33 which are drawn to 'an expression vector comprising HBEGF and an IRES site' (response filed on 2/5/03), which is different from the initially examined group. Thus, examiner apologizes for the confusion and would like to withdraw claims drawn to vectors which have components other than HBEGF and GFP and reinstate the species election.*

2. Newly submitted claims 21-24, 28-31 and 32-37 (in-part) are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the originally examined claims are drawn to vectors comprising HBEGF and GFP (only one selection gene), and the newly added claims 21-24, 28-31 and 32-37 (in-part) do not have GFP in addition to the HBEGF.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-24, 28-31 and 32-37 (in-part) are withdrawn from consideration as being directed to a non-elected invention. See 37 CAR 1.142(b) and MPEP § 821.03.

Claims 13-20 and 25-27, 32-37 (in-part) are currently are being examined in this application.

NOTE the original claims are examined as having only one selection gene (GFP). Thus all the claims drawn to more than one selection gene would not be examined in this application.

### ***Election/Restriction***

3. This application contains claims directed to the following patentably distinct species of the claimed invention: Applicants are requested to elect a single species of each of the following:

- a) Applicants are requested to elect a single species between 2a site and CD9 site;
- b) Applicants are requested to elect a single species of promoter;
- c) Applicants are requested to elect a single species of GFP.

**For this response to be complete and for search purposes,** Applicant is required under 35 U.S.C. 121 to **elect a single invention** (i.e., single expression vector, in which the specific components are all defined; and the relationship between the components by position and/or

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order of arrangement) or **a diagram of the vector representing each of the components and the elected species** for prosecution on the merits..

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CAR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CAR 1.143).
5. Applicant is required to reply to this restriction requirement within 30 days of mailing this action. See MPEP 809.2(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on *Increased Flex Schedule* and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri  
Patent Examiner  
Technology Center 1600  
Art Unit 1639  
25 August 2003

  
PADMASHRI PONNALURI  
PRIMARY EXAMINER